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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,694	10/18/2005	Yoshitaka Izumoto	IZUMOTO 1	2025

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EXAMINER	
DUFFY, PATRICIA ANN	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,694	IZUMOTO ET AL.	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 23-77* is/are pending in the application.

4a) Of the above claim(s) *51-62, 66-77* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,23-50 and 63-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10-18-05* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2X2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The responses filed 4-10-07 and 7-24-07 have been entered into the record. Claims 1 and 23-77 are pending. Claims 2-22 have been cancelled.

The preliminary amendment filed 10-18-05 is not in compliance with 37 CFR 1.121. There are two claims numbered 49. The second claim on page 20 has been renumbered claim 69, pursuant to rule 37 CFR 1.126. Appropriate correction should be provided in the next amendment to the claims.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

The drawings in this application have been accepted. No further action by Applicant is required.

Specification

The disclosure is objected to because of the following informalities:

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Information Disclosure Statement

The information disclosure statements filed 9-11-06 and 9-12-06 have been considered. Initialed copies are enclosed.

Election/Restrictions

Applicant's election with traverse of Group I, specie the chaperonin GroEL and serotonin receptor 5-HT1aR in the responses filed 4-10-07 and 7-24-07 is acknowledged. The traversal is on the ground(s) that there is no serious burden according to MPEP 803. This application has been filed under 35 USC 371. The criteria for lack of unity of invention is governed by PCT Rule 13.1 and not MPEP 803 which covers inventions filed under 35 USC 111. The issue in PCT Rule 13.1 is lack of a technical feature that defines over the art. In the instant case there is no technical feature that is "special" within the meaning of PCT Rule 13.2 as set forth in the last office action. With regard to rejoinder: Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. ***Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.*** Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. ***Failure to do so may result in a loss of the right to rejoinder.*** Further, note that the prohibition against double

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The requirement is still deemed proper and is therefore made FINAL.

Claims 51-62, 66, 67 (non elected species) and claims 68-77 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the response filed 4-7-07.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 27 and every claim dependent thereon are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 27, the claim recites that the folding factor is a chaperoning consisting of a plurality of chaperonin subunits. It is not clear if this recitation is intended to limit the type of folding factor or the number of folding factor copies. Further, "consisting of a plurality of chaperonin subunits" is indefinite..; because the closed language of "consisting of" is inconsistent with recited plurality being unlimited and open in nature. Clarification is requested.

Claim Rejections - 35 USC § 102 and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 25, 26, 27, 28, 29, 30, 33 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Fersht et al (WO 00/75346, 14 December 2000).

Fersht et al teach fusions proteins comprising a fragment of a chaperon polypeptide (GroEL) and a protein of interest wherein the fusion protein is produced as a gene construct (T7 promoter-ribosome binding site-(His6)-GroEL-Thr.site-cloning site for desired protein-terminus; Figure 1 and see abstract and pages 30-32, Examples 1 and 2). Fersht et al teach that GroEL is a tetradecamer wherein each monomeric subunit has a molecular weight of approximately 57kD. The tetradecamer facilitates in vitro folding of a number of proteins which would otherwise missfold or aggregate and precipitate. The structure of GroEL from E. coli has been established through X-ray crystallographic studies. The holo protein is cylindrical, consisting of two seven-membered rings that form a large central cavity which according to the art is essential for activity. (page 1, lines 22-31).

As such, Fersht et al anticipate the instant claims.

Claims 1, 25, 26, 27, 28, 29, 30, 33 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Scholz et al (WO 03/000878, published 3 January 2003).

Scholz et al teach fusion protein immunogens comprising two chaperonins produced by recombinant technology where the fusion comprises chaperonin-antigen-chaperonin wherein at least one linkage is a peptide liner of 10-100 amino acids (claim 14) wherein the linker comprises a proteolytic cleavage site (claim 20) wherein the polypeptide is a polypeptide from an infectious organism and used for immunization and is combined with a pharmaceutically acceptable excipient (see claims 21-26). Target polypeptides are described at pages 6-7 including human gene products.

As such the claims are anticipated.

Claims 1 and 23-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Furutani et al (WO 02/052,029, published 04 July 2002) in light of Furutani et al US 7,276,355 which is an English language equivalent of the WO document).

Furutani et al teach fusion proteins comprising GroEL chaperonin subunits from 1-7 in a fusion protein with target protein produced by recombinant means wherein the target protein is fused N or C terminal or both with a chaperonin and at least two subunit chaperonins are linked by a peptide bond (see Figure 2, elements 2-4; Figure 3 and Figure 7). The fusion protein comprises 1-20 chaperonin subunits liked to on another and a desired protein linked via the N-terminus or the C-terminus. The fusion protein has at least one linking region where the linking region may be cleaved by a restriction protease to release the target protein. Furutani et al teach there is a fusion protein comprising chaperoning subunits and a desired protein being linked by a peptide linkage to the chaperoning subunits is accommodated inside of the chaperonin ring. The chaperonin ring may have formed a 2 layer structure associated non-covalently via a ring plane. The chaperonin used is not particularly limited and may be derived from bacteria, archaeum and eukaryotes and includes GroEL (Example 8). The desired protein is not particularly limited and includes the serotonin receptor (5H1A) fusion protein with GroEL (Example 8). A sequence to be cleaved with a restriction protease such as thrombin, enterokinase or active blood coagulation factor can be arranged in a linkage between the chaperoning subunit and the desired protein and also in a linkage between the chaperonin subunits to cleave the desired protein off the fusion protein with the restriction protease.

Claims 63-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Furutani et al (WO 02/052,029, published 04 July 2002) in view of Scholz et al (WO 03/000878, published 3 January 2003) and Harlow et al, (Antibodies A Laboratory Manual, Cold Spring Harbor Press, 1988, Ch. 5, pages 53-137)

The teachings of Furutani et al are set forth supra. Furutani et al differs by not teaching the fusion protein combined with an adjuvant.

Scholz et al teaches chaperonin fusion proteins are useful for the production of a vaccine immunogenic or pharmaceutical composition.

Harlow et al teach conventional adjuvant formulations to make immunogenic vaccine compositions for antibody production (see pages 96-99).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to add an adjuvant to the fusion protein compositions of Furutani et al because Scholz et al teach that chaperonin fusion proteins can be used as immunogens for vaccines.

Status of the Claims

Claims 1, 23-50 and 63-65 stand rejected. Claims 51-62, 66, 67 (non elected species) and claims 68-77 are withdrawn.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 7:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Shanon Foley can be reached on 571-272-0898.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Patricia A. Duffy/

Patricia A. Duffy, Ph.D.

Primary Examiner

Art Unit 1645